Complete Summary

GUIDELINE TITLE

Knee pain or swelling: acute or chronic.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Knee pain or swelling: acute or chronic. Ann Arbor (MI): University of Michigan Health System; 2005 Apr. 13 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Knee pain or swelling: acute or chronic. Ann Arbor (MI): University of Michigan Health System; 2002 Aug [rev. 2004 Oct]. 13 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the Food and Drug Administration (FDA) asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Most recently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA

determines pose a serious and significant public health concern. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Knee pain or swelling (acute or chronic)

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Orthopedic Surgery
Pediatrics
Rheumatology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To facilitate a comprehensive, yet efficient evaluation of knee pain
- To recommend appropriate use of knee X-rays and magnetic resonance imaging (MRI)
- To provide optimal treatment of knee pain
- To identify indications for consultation

TARGET POPULATION

Children, adolescents, and adults with knee pain

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Comprehensive history and physical
2. Laboratory and ancillary tests
    - Blood studies (e.g., complete blood count, sedimentation rate, fungal, tuberculosis, or bacterial cultures)
    - Synovial fluid analysis (e.g., cell count, crystals, fungal, tuberculosis, or bacterial cultures)
    - Arthrocentesis/aspiration
    - X-ray
    - Magnetic resonance imaging (MRI)
    - Vascular studies

Treatment/Management

1. Pain/inflammation control
    - Topical treatment
        - Ice
        - Capsaicin
    - Oral
        - Acetaminophen
        - Salicylates
        - Traditional non-steroidal anti-inflammatory drugs (NSAIDs
        - Cyclooxygenase-2 (COX-2) inhibitors
        - Combination preparations such as diclofenac sodium & misoprostol
        - Alternative medicine such as glucosamine and chondroitin
    - Intraarticular injection
        - Hyaluronic acid (HA) injections
        - Anesthetics
        - Corticosteroids

2. Activity modification
    - Biomechanical assessment
    - Restriction and/or rest
    - Knee padding
    - Extension splints
    - Crutches
3. Therapeutic exercise
    - Quadriceps strengthening
    - Hamstring and calf stretching
    - Knee strengthening
    - Low impact aerobics
4. Referral to specialist

MAJOR OUTCOMES CONSIDERED

- Utility of diagnostic tests for evaluating knee pain
- Degree of pain relief
- Physical functioning
- Drug interactions and side effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search was conducted prospectively using the major keywords of knee injuries, knee, patellofemoral, patello, anterior cruciate ligament, meniscus, meniscal tear, osteoarthritis, brace(s), immobilizer, immobilization, rehabilitation, x-rays, computed tomography, radiography, magnetic resonance imaging, MRI, diagnosis, treatment, randomized controlled trial, clinical trials, controlled clinical trial(s), meta-analysis, multicenter studies, comparative study(ies). Articles between 1976 and December 1996 were examined. The search was supplemented with recent clinical trials known to expert members of the panel. Negative trials were specifically sought.

Literature searches on three new topics were used to update the guideline: COX-2 inhibitors (cyclooxygenase inhibitors), hyaluronic acid, and glucosamine/chondroitin sulfates. Publications from July 1996 through available in April 2000 were examined. The following main terms were included in each of the three searches: knee, knee joint, knee medical collateral ligament, knee injuries, patella-injuries, knee-injuries, knee osteoarthritis, osteoarthritis, pain. Searches also included the following terms to identify the type of information provided: guidelines, clinical trials, and costs. (Specific Medical Subject Heading [MeSH] search terms are available upon request from the guideline developer.) The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials

D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trails if available, to the exclusion of other data. If randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consideration of benefits, harms, costs, and patient preferences

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership and in clinical conferences of departments to which the content is most relevant. This guideline concerning knee pain was reviewed by members of the following departments or divisions: Emergency Medicine Family Medicine, General Medicine, OrothoPedic Surgery, Adult Rheumatology, and Pediatric Rheumatology, Guidelines are approved by the Executive Committee for Clinical Affairs.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text of the original guideline document for additional information, including detailed information on dosing, possible side effects, and cost of medications; risk factors; and subspecialty referrals.

The levels of evidence (A, B, C, D) are repeated at the end of the Major Recommendations field.

Diagnosis

The majority of knee pain is caused by patellofemoral syndrome and osteoarthritis [evidence: D].

Magnetic resonance imaging (MRI) of the knee has been proven not to be superior to the clinical exam by an experienced examiner in the evaluation of acute knee injuries [A].

Magnetic resonance imaging may be useful to assess bone pathology underlying chronic knee pain [D].

Differentiating between knee pain without constitutional symptoms, knee pain with constitutional symptoms, and traumatic knee pain is helpful in determining a diagnosis (refer to Figures 1, 2, and 3 in the original guideline document for details).

Patients with knee pain and swelling who have non-bloody aspirates may also have serious knee pathology (refer to Figure 4 in original guideline document for details).

Treatment

Exercises are important. Many knee conditions will improve with conservative treatment consisting of low-impact activities and exercises to improve muscular strength and flexibility. Patellofemoral dysfunction is best treated with vastus medialis strengthening and hamstring and calf stretching [B].

In most cases a home treatment program should be explained in detail to the patient, including specific guidelines for activity modification and exercises. Initially, formal physical therapy is usually not required.

All patients with mild to moderate knee osteoarthritis who do not have medical contraindications should be offered an exercise program that includes lower extremity strengthening and stretching exercises combined with low impact aerobic exercises (e.g., swimming, biking, walking, cross-country skiing) [A].

The initial drugs of choice for the treatment of the pain of knee osteoarthritis are acetaminophen and/or topical capsaicin [A]. If a traditional non-steroidal anti-inflammatory drug (NSAID) is indicated, the choice should be based on cost (refer to Table 6 in original guideline document for details). Cyclooxygenase-2 (COX-2) inhibitors are no more effective than traditional NSAID agents; they may offer a

short-term but probably no long-term advantage in gastrointestinal (GI) tolerance for some patients. Due to cost and increased heart attack risk, COX-2 inhibitors should be reserved for carefully selected patients (refer to Table 7 in the original guideline document for details).

Follow-up

Symptoms should not be allowed to persist for more than 12 weeks before a reevaluation of the condition, along with possible consultation with physical therapy or a musculoskeletal specialist (e.g., orthopedic surgeon, rheumatologist, physiatrist, or sports medicine specialist) [D].

Definitions:

Levels of Evidence

Levels of evidence for the most significant recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

The original guideline document contains clinical algorithms for:

- Knee Pain without Constitutional Symptoms
- Knee Pain with Constitutional Symptoms
- Traumatic Knee Pain
- Knee Effusion that is Not Grossly Bloody

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major Recommendations).

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Comprehensive and efficient evaluation of knee pain

- Appropriate use of knee x-rays and magnetic resonance imaging (MRI) in evaluating knee pain
- Optimal treatment of knee pain
- Improved identification of patients in need of specialty consultation or referral

POTENTIAL HARMS

Adverse Treatment Effects

- Non-steroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-2 (COX-2) inhibitors: There is a potential for gastrointestinal side effects, including gastrointestinal bleeding, with both classes of drugs. Analyses of major trials of COX-2 inhibitors demonstrate an increase in cardiovascular event rates for patients taking COX-2 inhibitors.
- COX-2 inhibitors should be used with caution in patients at high risk for atherosclerotic disease until further studies clarify the potential risks.
- Both glucosamine and chondroitin appear to be quite safe with few side effects, particularly in comparison to NSAIDs. The chondroitin sulfate molecule is similar in structure to heparin, and may interact with anti-coagulation medications.
- Intraarticular injection: Potential side effects include introduction of infection, skin necrosis, tendon and cartilage weakening, and systemic effects of corticosteroids (especially hyperglycemia).
- Hyaluronic acid injection: Adverse effects with intraarticular hyaluronic acid injections occur in about 8% of patients and are limited usually to a mild, self-limiting local reaction.

CONTRAINDICATIONS

CONTRAINDICATIONS

Non-steroidal Anti-inflammatory Drugs (NSAIDs)

Traditional NSAIDs should not be given to patients with documented intolerance to traditional NSAIDS or risk factors for gastrointestinal bleeding, such as: (1) a history of upper gastrointestinal bleeding, (2) receiving chronic, high dose systemic corticosteroids, or (3) presence of a bleeding disorder.

Cyclooxygenase-2 (COX-2) Inhibitors

- Celecoxib is contraindicated in sulfa-allergic patients.
- COX-2 inhibitors should usually be avoided in patients with cardiac risk factors.
- Do not prescribe COX-2s to patients with known coronary heart disease.

QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Foreign Language Translations
Patient Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Nov (revised 2005 Apr)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Knee Pain Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Guidelines Oversight Team: Connie Standiford, MD; Lee Green, MD, MPH; Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following are available:

- Patellofemoral pain syndrome rehabilitation exercises. University of Michigan Health System; 2002 Aug. Various p. Electronic copies: Available from the University of Michigan Health System Web site. Spanish version also available from the University of Michigan Health System Web site.
- Patellofemoral pain syndrome rehabilitation exercises. University of Michigan Health System; 2002 Aug. Various p. Electronic copies: Available from the University of Michigan Health System Web site.

NGC STATUS

This NGC summary was completed by ECRI on March 19, 2003. The information was verified by the guideline developer on April 23, 2003.

This guideline was updated by the guideline developer in October 2004 following the removal of Vioxx (rofecoxib) from the worldwide markets. The guideline was updated again by the guideline developer in December 2004 following the release of a public health advisory from the U.S. Food and Drug Administration (FDA) regarding the use of some non-steroidal anti-inflammatory drug products (NSAIDs) This summary was updated on April 14, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was most recently updated on September 21, 2005. The updated information was verified by the guideline developer on November 1, 2005.

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